Application/Control Number: 08/932,227

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IFW contains an entry "Claims" apparently filed 8-6-09 and numbered as pages 21 and 22, i.e. the next highest number following page 20 of applicants substitute specification and with the heading "Patent claims" on pages 21 and 22. These two pages are clearly not the accurate substitute claims pages of the specification as filed but based on the page numbering and heading "Patent claims" (and no further identification as well as the tabulation by support staff of these pages as "Claims") it appears (?) that possibly applicants have submitted these pages as substitute claims pages. As these pages are not remotely accurate renditions of the claims as filed (or any other copy of the claims as filed during prosecution), applicants substitute specification has not yet been entered pending clarification of the "Patent claims". A substitute copy of the claims is not necessary. However, in order to avoid confusion applicants are requested to reiterate the claims as now of record if they do not amend their claims in response to this Office action. In any case applicants are requested to explain the "Patent claims" submitted on 8-6-09 so that the Examiner can instruct the support staff to take corrective action to IFW if needed. If the "Patent claims" were indeed meant to be part of the newly filed substitute specification then the specification will remain unentered and a new substitute specification should be filed absent any substitute claims pages as part of the substitute specification. Given applicants statement that no changes other than paragraph numberings have been made relative to the previous version, no marked up copy is needed

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The foreign patents DE 10128910, FR 2810540 and FR 1553063 have not been submitted with the concise explanation required for foreign language references and have therefore not been considered, MPEP 609.

Claim 61 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mentrup et al. (US 5,498,420). Patentees disclose a "liposome" (title) containing an esterified "collagen hydrolysate" (abstract; a material inherently expected to contain arginine in possibly chemically combined form). The liposome penetrates into deep skin layers at column 3, lines 1-10. The examiner realizes that the collagen may well be in the liposome walls but nonetheless can be viewed as "within the packaging" as required by the claims. Note in this regard that the active agent of the patent is also found in the vesicle walls or membranes but is nonetheless said to be encapsulated in patent claim 16 and 17. With regard to applicants limitation "released from the packaging and absorbed by the tissue" this is presumably inherent in that it is not expected that the vesicle once absorbed by the skin would be infinitely long lived in the skin. Note the examples containing electrolytes such as sodium phosphate (column 23) such as would reasonably appear to create a hostile biophysical environment given that applicants specification discloses that such an environment may be created by electrolytes.

. When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently

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possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note <u>In re Fitzgerald et al.</u> 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

Ghosh (US 2007/0105763), cited of interest discloses that arginine is present in collagen at paragraph 238.

Claims 62 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

It is noted that Mausner, newly cited by applicants uses protein hydrolysates.

However Mausner does not otherwise teach or suggest the combination of limitations of applicants claims.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis M-F, 9-5 pm at telephone number 571 272 1075.

Jeffrey C. Mullis Primary Examiner Art Unit 1796

JCM

10-24-09

/Jeffrey C. Mullis/

Primary Examiner, Art Unit 1796